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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,606	02/21/2006	Hans G. Boman	3612.1001-000	9912

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,606	BOMAN ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12,14-20,22,23,25-27,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12,14-20,22,23,25-27,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 8 August 2007, is acknowledged. Claims 1, 9, 10, 19, 20, 22, 23, 25, 31, and 32 have been amended. Claims 2, 21, 24, 29, 30 have been canceled.

2. Claims 1, 3-12, 14-20, 22, 23, 25-27, 31, and 32 are pending and under consideration.

Rejections/Objections Moot or Withdrawn

3. The objection to claim 22 is withdrawn in light of the amendment of the claim.

4. The rejection of claims 2, 21, and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for "levels" is moot in light of the cancelation of the claims.

5. The rejection of claims 29 and 30 under 35 U.S.C. 112, first paragraph, scope of enablement for compositions for or methods of treatment *in vivo*, is moot in light of the cancelation of the claims.

6. The objection to Figure 2 is withdrawn in light of the amendment of the Figure.

7. The rejection of claims 1, 3-8, 10-12, and 20, 22, 23, and 25-27 under 35 U.S.C. 112, second paragraph, as being indefinite for "levels" is withdrawn in light of the amendment of the claims.

Rejections Maintained

8. The rejection of claims 1, 3-8, 10-12, and 20, 22, 23, and 25-27 under 35 U.S.C. 112, second paragraph, as being indefinite for "levels" is maintained.

Applicants argue that the amendment of the claims obviates the rejection because now the claims recite a comparison of LL-37 levels to a normal subject.

The examiner has considered applicants' argument, and finds it persuasive in part. Now the assay methods due recite a comparison to a "normal subject". However, the claims remain

reciting "a method for determining the susceptibility of a subject to infection", and that no LL-37 or a lowered level of LL-37 "indicates that said subject is susceptible to infection". Thus, does this mean that if a subject has normal levels of LL-37, than that subject is impervious to any/all infections? The specification does not teach this. Instead, the specification teaches that a subject exhibiting no LL-37 or low levels of LL-37 compared to a control subject has an "increased susceptibility" to infection. Thus, it is unclear if a "normal" subject is totally impervious to infection, or one who has a "decreased susceptibility" to infection.

9. The rejection of claims 9, 14-19, and 31 and now newly amended claim 32 under 35 U.S.C. 112, first paragraph, scope of enablement for compositions for or methods of treatment *in vivo*, is maintained for reasons of record.

Applicants argue that the specification teaches that lowered levels of LL-37 increases the susceptibility of the individual to infection, and that LL-37 may be administered to said individual to compensate for the lack of naturally expressed LL-37 in order to treat/prevent infection in those individuals.

The examiner has considered applicants' argument, but does not find it persuasive. As stated in the original rejection explanation, at the time of filing of the instant application, the art did not provide clinical or experimental *in vivo* information concerning treatment of infection or prophylactic administration of LL-37 to subjects. Thus, there is a lack of predictability in the art for treatments of subjects by administration of LL-37. The instant specification provides no dose regimen, composition parameters, effective dose levels needed for *in vivo* efficacy, or tissue availability, only *in vitro* assays. Thus, there is insufficient support for the scope of the instant claims, i.e., methods of *in vivo* treatment of individuals.

As newly amended, claim 32 is now drawn to the method of claim 31. If this form of claim 32 were present in the original presentation, it would have been included in the original rejection.

Notation

10. It is noted that concerning Figure 2, the brief description and the specification describe only four of the five linear depictions shown in the Figure. What is the fifth linear depiction utilizing dotted lines with squares?

Conclusion

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection of claim 32 presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's acting Supervisor, Bruce Campell, can be reached on (571)272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

October 23, 2007